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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,996	02/05/2004	Shiv Kumar	PB0311	5385

7590 09/19/2006

Amersham Biosciences Corp  
800 Centennial Avenue  
Piscataway, NJ 08855

EXAMINER
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BABIC, CHRISTOPHER M

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/772,996	<b>Applicant(s)</b> KUMAR ET AL.	
	<b>Examiner</b> Christopher M. Babic	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-64 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, drawn to a method of increasing the rates of an enzyme catalyzed nucleoside monophosphate transfer from a terminal-phosphate-labeled nucleoside polyphosphate classified in class 435, subclass 6, for example.
- II. Claims 13-39 and 45-49 drawn to a method of detecting the presence of a nucleic acid sequence classified in class 435, subclass 6.
- III. Claims 40-44 and 50-54, drawn to a nucleic acid detection kit, classified in class 435, subclass 975, for example.
- IV. Claims 55-64, drawn to a terminal-phosphate labeled nucleoside polyphosphate and kits thereof, classified in class 536, subclass 23.2, for example.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions I and II are independent and distinct from one another because they are different methods requiring separate reaction parameters and components. For example, the ultimate goal of both methods is different. Group I recites a method of a method of increasing the rates of an enzyme catalyzed nucleoside monophosphate

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transfer from a terminal-phosphate-labeled nucleoside polyphosphate, while group II recites a method of detecting the presence of a nucleic acid sequence. Group II, unlike group I, requires the presence of a target nucleotide sequence as well as a phosphatase. Each of these groups requires their own unique examination considerations.

Furthermore, searching groups I and II together would impose a serious search burden. First, since the ultimate goal of both methods is different, the search is not necessarily coextensive. For example, a search for the method of group I would not necessarily methods requiring a nucleic acid polymerase reaction containing a target nucleotide sequence as well as a phosphatase.

Because these inventions are distinct for the reasons given above and the search of groups I and II together would result in a significant search burden, restriction for examination purposes as indicated is proper.

2. Inventions III and IV, and I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the products of groups III, IV, and V can be used in a wide variety of materially different generic biochemical processes such as amplification assays (e.g. PCR, for example), sequencing assays (e.g. Sanger, for example), etc.

Furthermore, searching groups III and IV, and I and II together would impose a serious search burden. First, groups I and III have obtained a separate status in the art as demonstrated by their different classifications. Moreover, each of these groups requires their own unique examination considerations. For example, groups III and IV require a search in the appropriate chemical structure databases, while a search for group I is done in a textual manner.

It is noted that a general chemical structure of group III does appear in group II, however, since products of groups III and IV can be used in a wide variety of materially different generic biochemical processes, the search of both groups III and IV, and I and II is not necessarily coextensive. A search for the specific chemical structures of groups III and IV would not necessarily encompass all or any of the process parameters required in groups I or II.

Because these inventions are distinct for the reasons given above and the search of groups I and III together would result in a significant search burden, restriction for examination purposes as indicated is proper.

3. Inventions III and IV are independent and distinct from one another because they possess different core chemical structures requiring separate chemical moieties unique to each invention. For example, group III requires a specific label structure containing specific chemical groups, while group IV requires a generic label structure in addition to a specific linker structure (x-Z-y) containing specific chemical groups and a manganese complex (Mn)<sub>x</sub>.

Furthermore, searching groups III and IV together would impose a serious search burden. Groups III and IV require a search in the appropriate chemical structure databases. Since they are different core chemical structures requiring separate chemical moieties unique to each invention, they each require a separate and distinct search and examination strategy.

Because these inventions are distinct for the reasons given above and the search of groups III and IV together would result in a significant search burden, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is

found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-

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272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



9/12/06

Christopher Babic  
Patent Examiner  
AU 1637

  
KENNETH R. HORLICK, PH.D.  
PRIMARY EXAMINER

9/14/06